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Prevention, Pesticides and Toxic Substances (7510P)

November 2009

Lauryl Sulfate Salts Summary Document: Registration Review

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Lauryl Sulfate Salts Registration Review: Initial Docket November 2009

Case # 4061

Approved By:

Joan Harrigan-Farrelly

Director, Antimicrobials Division

Date:

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Lauryl Sulfate Salts Registration Review Team

Human Health & Environmental Effects

William J. Hazel A. Najm Shamin

Risk Management Monisha Harris

Lance Wormell

Office of General Counsel

Philip Ross

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I. PRELIMINARY WORK PLAN

Introduction

The Food Quality Protection Act (FQPA) of 1996 mandated a registration review program. All pesticides distributed or sold in the United States generally must be registered by the U.S. Environmental Protection Agency (USEPA, EPA, or the Agency), based on scientific data showing that they will not cause unreasonable risks to human health (including occupational and non-occupational exposures) or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at http://www.epa.gov/oppsrrd1/registration_review/.

The Agency is implementing the registration review program pursuant to Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop and commit to a final work plan and schedule for the registration review of lauryl sulfate salts. Lauryl sulfate salts is also known as sodium lauryl sulfate and the terms are used interchangeably throughout this document and the support documents.

Sodium lauryl sulfate is the only active ingredient in case 4061 and there is only one registered product that contains sodium lauryl sulfate as an active ingredient. Products containing sodium lauryl sulfate as an active ingredient were first registered in 1948. It is widely used as an intentionally-added inert ingredient in pesticide products and is one of two active ingredients included as an antiviral compound in Kleenex® Brand Antiviral Tissues; the PC Code is 079011. The antiviral tissues contain 2.02% sodium lauryl sulfate and are registered by Kimberly-Clark Global Sales, LLC (EPA Reg. No. 9402-10). The tissues also contain citric acid as an active ingredient at 7.51%. A manufacturing-use product containing sodium lauryl sulfate has not been registered.

Sodium lauryl sulfate is widely used as a surfactant added to lower the surface tension of other substances and is also used as an emulsifier, whipping agent, or wetting agent. However, it is by far much more widely-used for industrial purposes because of these surface-active properties.

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EPA has established exemptions from the requirements of a tolerance for residues of sodium lauryl sulfate in foods [40 CFR 180.940(a), -(b), and -(c)] due to the low toxicity. The Food and Drug Administration (FDA) has classified sodium lauryl sulfate as both a direct and indirect food additive. It is Generally Recognized as Safe (GRAS) when directly-added to eggs, marshmallows, beverages, and oils (21 CFR 172.822) at up to 125 ppm as an emulsifier, whipping agent, surfactant, or wetting agent. Other FDA-regulated uses include: a citrus coating (21 CFR 172.210); a component of food contact paper and paperboard [21 CFR 176.170(a)(5)]; a defoaming agent component of food contact paper and paperboard [21 CFR 176.210(d)(3)]; and an emulsifier or other surface active agent during manufacture of articles intended for food contact [21 CFR 178.3400(c)].

A Reregistration Eligibility Decision (RED) for lauryl sulfate salts was issued in September 1993.

Risk Assessment Status & Anticipated Risk Assessment and Data Needs

Human Health Risk Assessment Status

The hazard and exposure databases and the available assessments for sodium lauryl sulfate were examined to determine whether they reflect the current state of the science, changing use patterns, and current policies/regulations/statutory requirements. The Agency has screened both the hazard and exposure databases for sodium lauryl sulfate and does not anticipate that additional toxicity or exposure data will be needed for registration review. The Agency also does not expect that any human health risk assessments will be necessary due to the low hazard and low exposure associated with the use of sodium lauryl sulfate as a pesticide - particularly when compared to the much higher levels of exposure from industrial, culinary, pharmaceutical, cosmetic, and personal care uses of this compound.

Further information on the human health risk assessment is available in the document titled, "Lauryl Sulfate Salts. Human Health Effects Scoping Document for the Registration Review Decision," dated December 07, 2009.

Toxicity

The toxicology database for sodium lauryl sulfate is adequate to support its use as an active or inert ingredient in pesticide formulations and to support the tolerance exemption for use as a component of food contact surface sanitizers. Sodium lauryl sulfate has low acute oral and dermal toxicity but is irritating to the skin and eyes at high doses. Sodium lauryl sulfate is not a skin sensitizer. Sodium lauryl sulfate was negative in tests for genotoxicity. The repeated dose toxicity data on alkyl sulfates including sodium lauryl sulfate demonstrate effects consistent with the irritation caused by other surfactants. The common target organs of toxicity following repeated-dose oral exposure were the forestomach in gavage studies, and the liver and kidneys in dietary studies.

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A no-observed adverse effect level (NOAEL) of 100 mg/kg/day was selected from a 28-day oral (gavage) study in rats in which decreased food consumption and decreased body-weight gain were observed at the lowest observed adverse effect level (LOAEL) of 200 mg/kg/day. Other subchronic studies showed similar results. No evidence of neurotoxicity was observed in any of the studies. Chronic toxicity data on sodium lauryl sulfate are limited but in two 2-yr rat feeding studies, no treatment-related effects were observed at doses up to approximately 100 mg/kg/day. From two carcinogenicity studies (summaries only available), testing closely-related alkyl (C_{12} - C_{15}) sulfonates; there is no evidence that sodium lauryl sulfate would exhibit carcinogenic potential when dosed at up to 1.5% of the diet.

No evidence of increased susceptibility was observed in the offspring of rats, rabbits, and mice following prenatal or postnatal exposure to sodium lauryl sulfate. In a developmental toxicity study with sodium lauryl sulfate in rats, rabbits, and mice, maternal toxicity and developmental toxicity were seen only at the highest dose tested of 600 mg/kg/day. The NOAEL for maternal and developmental effects in that study was 300 mg/kg/day. There was no evidence of neurotoxicity in the adult animals. A 2-generation reproductive toxicity study conducted with a related chemical, α -alkyl (C_{12}) olefin sulfonate, showed no treatment-related adverse reproductive effects and no systemic adverse effects on organs at dose levels up to 285 mg/kg/day (high dose therapy).

Dietary and Drinking Water Assessment

Dietary Food Exposure

Human dietary (food) exposure is not expected to occur from the use of antiviral tissues, the only registered use of sodium lauryl sulfate as an active ingredient.

FDA classifies sodium lauryl sulfate as being GRAS when used as a direct food additive (for nonpesticidal purposes) at concentrations as high as 125 ppm when ready to consume, e.g., as an emulsifier in frozen or liquid egg whites. EPA has established exemptions from the requirements of a tolerance for residues of sodium lauryl sulfate in foods [40 CFR 180.940(a), -(b), and -(c)] due to the low toxicity.

Dietary Drinking Water Exposure

Dietary exposure to sodium lauryl sulfate via drinking water is not likely to occur based on its only registered use as an active ingredient in antiviral tissues. Even if the antiviral tissues or their leachate were to reach the outdoor environment, the intact parent compound would be metabolized rapidly by aquatic and soil microbes and is not expected not persist to the point it could be consumed in drinking water. Metabolites of sodium lauryl sulfate (sulfate and acetate anions) are not of toxicological concern.

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Tolerances

Sodium lauryl sulfate serves as an intentionally-added inert ingredient in over 370 pesticide products although few of these are antimicrobial products. Sodium lauryl sulfate is exempt from the requirement of a tolerance when used as an inert ingredient in food contact sanitizer products provided that the final treatment solution used: in public eating places contains \leq 3 ppm; on dairy processing equipment contains \leq 350 ppm; and on food processing equipment and utensils has no limit [40 CFR 180.940(a), -(b), and -(c), respectively]. Residues of alkyl (C₈-C₁₈) sulfates, including sodium lauryl sulfate, are exempt from the requirement of a tolerance when used as inert ingredients (surfactants) in pesticide formulations applied to growing crops or to raw agricultural commodities (RACs) after harvest (40 CFR 180.910) or to animals (40 CFR 180.930).

Aggregate and Cumulative Exposure

In examining aggregate exposure, EPA takes into account available and reliable information concerning exposures to pesticide residues in food and drinking water, as well as non-occupational pesticide exposures. EPA does not have, at this time, available data to determine whether sodium lauryl sulfate has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this Registration Review, EPA has assumed that sodium lauryl sulfate does not have a common mechanism of toxicity with other substances when used as an antimicrobial as registered.

Occupational and Residential Assessment

A quantitative risk assessment is not required because, based on the use pattern (antiviral tissues) and low toxicity of sodium lauryl sulfate, adverse systemic effects on humans attributable to the dermal and inhalation routes of exposure to sodium lauryl sulfate are not expected.

Incidents

Since its registration in 1948, one human incident associated with human exposure to sodium lauryl sulfate has been reported. The symptoms included blisters on the face and nose that remained for 3.5 weeks after exposure. There are 76 incidents associated with lauryl sulfate involving domestic animals which most commonly manifested in hair loss, difficulty breathing, and rashes.

Environmental Fate and Ecological Risk Assessment Status

The Agency reviewed the environmental fate and ecological hazard data for sodium lauryl sulfate. Based on the low hazard and exposure the Agency anticipates concluding that the registered uses of sodium lauryl sulfate will have "no effect" (NE) on endangered or threatened terrestrial or aquatic species, or their designated critical

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habitats, as listed by the U.S. Fish and Wildlife Service (USFWS) and the National Oceanic and Atmospheric Administration's (NOAA) National Marine Fisheries Service (NMFS). EPA anticipates conducting no further analysis of potential risks to endangered or threatened species unless public comments provide additional information that would alter the Agency's current position that sodium lauryl sulfate will have "no effect" on such species or their designated critical habitat.

Further information on the environmental fate and ecological risk assessment is available in the document titled, "Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Lauryl Sulfate Salts Registration Review Decision Document," dated October 15, 2009.

Anticipated Physical/Chemical Property Data Needs

The product chemistry data for Sodium lauryl sulfate is adequate and the Agency does not anticipate requiring additional product chemistry studies at this time.

Table 1: Physical and Chemical Properties of Lauryl Sulfate Salts

| Guideline No./ Study Type | Results | MRID No./ Reference Information |
|--|---|---------------------------------------|
| 830.6302 Color | The TGAI is white in color. The product is clear watery solution. | 44805201 |
| 830.6303 Physical state | The TGAI is solid at room temperature. The product is a liquid at room temperature. | 44805201 |
| 830.6304 Odor | The TGAI and product are odorless. | 44805201 |
| 830.6313 Stability to normal and elevated temperatures, metals, and metal ions | Sodium lauryl sulfate is stable | 44805201 |
| 830.6314 Oxidation/reduction | This product does not contain an oxidizing or reducing agent. | 44805201 |
| 830.6315 Flammability | This product does not contain combustible liquids | 44805201 |
| 830.6316 Explodability | This product is not potentially explosive. | 44805201 |
| 830.6317 Storage stability | The product is stable beyond one year. | 44805201 |
| 830.6319 Miscibility | This product is not an emulsifiable liquid. | 44805201 |
| 830.6320 Corrosion characteristics | The corrosion characteristics have not been determined/not applicable | 44805201 |
| 830.6321 Dielectric breakdown voltage | This product is not intended for use in or around electrical equipment | 44805201 |
| 830.7000 pH | 8.5 to 9.0 (product) | 44805201 |

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| Guideline No./ | MRID No./ | |
|---|--|-------------|
| Study Type | | Reference |
| | | Information |
| 830.7100 | The viscosity of this product has not been determined. > 97% | 44805201 |
| Viscosity | aqueous solution; likely to have the viscosity close to water. | |
| 830.7200 | 205.5 ° C | RD Memo |
| Melting point | | |
| 830.7220 | Not applicable for TGAI | 44805201 |
| Boiling point | | |
| 830.7300 | The density of this product is not determined | OECD SIDS |
| Density | OECD/SIDS: 0.6 g/cc | Document |
| 830.7370 | This is not determined; not applicable | 44805201 |
| Dissociation constant | | |
| 830.7550 | Highly water soluble. | RD Memo |
| Partition coefficient (K _{OW)} | $\log K_{\rm OW} = 1.6.$ | |
| 830.7860 | TGAI: 150 g/L | 44805201 |
| Solubility | | |
| 830.7950 | 11 x10 ⁻¹² mm Hg at 25 °C | RD Memo |
| Vapor pressure | | |

Environmental Fate and Ecological Risk Assessment Status and Data Needs

Environmental Fate and Transport Data

The registered use of lauryl sulfate is in antiviral tissue paper at 2% as an active ingredient. It is primarily an indoor use and is not likely to end up in the wastewater streams. Moreover, the Organisation for Economic Co-operation and Development's (OECD) SIDS (Screening Information Data Set) document on sodium lauryl sulfate lists this chemical as one that is readily biodegradable. Available data indicate that sodium lauryl sulfate degrades up to 60-70% in less than ten days in wastewater treatment plants, and 100% within 3 days in a river. Alkyl sulfates (including lauryl sulfate) is biodegradable with a half life of 0.75 days. With an estimated $K_{OC} = 10,000$ is not likely to be mobile from soil surfaces.

Since this chemical is readily biodegradable, the Agency does not anticipate requiring additional environmental fate data for sodium lauryl sulfate for this registration review.

Ecological Effects Data Summary

Ecotoxicity data on lauryl sulfate salts aka sodium lauryl sulfate were generated in the 1980s by ORD's Cincinnati Labs. Table 2 summarizes the acute/ long term ecotoxicity data on various species.

Table 2: Ecotoxicity Acute and Long-term Data on Various Aquatic Species

| Ecotoxicity | Species | Method Used | Results | Remarks (EECs) |
|------------------------------|----------------------|----------------------|------------------------------|--------------------|
| Acute and Chronic to fish | Menidia Beryllina | EPA-600/4- 87/028 | LC_{50} (7 days) = 1.8mg/L | Salt Water species |

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| | (larvae) | | | |
|--|----------------------|----------------------|-------------------------------|------------------------|
| Acute/Chronic to aquatic invertebrates (daphnia) | Brachionus rubens | EPA-600/4- 85/013 | EC_{50} (48 hr) = 1.8 mg/L | Fresh water species |
| Aquatic plants; e.g. algae | Champia parvula | EPA 600/4- 87/028 | EC_{50} (48 hr) = 0.30 mg/L | Salt Water Species |
| Chronic to aquatic invertebrates (daphnia) | Daphnia Magna | EPA-600/3-75- 009 | NOEC (40 days) = 2 mg/L | Fresh Water Species |

Since the chemical is readily biodegradable, the Agency does not anticipate the need to require additional ecological toxicity data for sodium lauryl sulfate for this registration review.

Timeline

The EPA has created the following estimated timeline for the completion of the sodium lauryl sulfate registration review case. The Agency anticipates requiring additional data and residential, occupational and ecological exposure assessments for this registration review case.

Anticipated Schedule

| Registration Review for Lauryl Sulfate Salts Projected Registration Review Timeline | | | |
|---|----------------|--|--|
| Activities | Time | | |
| Opening Docket | | | |
| Open Public Comment Period for Lauryl Sulfate Salts Docket | December 2009 | | |
| Close Public Comment Period | March 2010 | | |
| Case Development | | | |
| Develop Final Work Plan (FWP) | March 2010 | | |
| Issue Final DCI | N/A | | |
| Data Submission | N/A | | |
| Open Public Comment Period for Preliminary Risk Assessments | N/A | | |
| Close Public Comment Period | N/A | | |
| Registration Review Decision | | | |
| Open Public Comment Period for Proposed RR Decision | March 2010 | | |
| Close Public Comment Period | May 2010 | | |
| Final Decision | September 2010 | | |
| Total (years) | 1 year | | |

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Guidance for Commenters

The public is invited to comment on the Agency's preliminary registration review work plan and rationale. The Agency will consider all comments as well as any additional information or data provided in a timely manner prior to issuing a final work plan (FWP) for the lauryl sulfate salts case.

Stakeholders are also specifically asked to provide available information and data in the following areas:

- 1. Confirmation on the following label information:
 - a. Sites of application
 - b. Formulations
 - c. Application methods and equipment
 - d. Maximum application rates
 - e. Frequency of application, application intervals and maximum number of applications
 - f. Geographic limitations on use
- 2. Use or potential use distribution
- 3. Use history
- 4. Usage/use information for non-agricultural uses (e.g., materials preservation)
- 5. Typical application interval
- 6. State or local use restrictions
- 7. Ecological incidents (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) not already reported to the Agency
- 8. Monitoring data
- 9. Structure Activity Relationships
- 10. Use information for the recirculating cooling tower systems use (e.g., industry standards, information on release rates and frequency of release of treated recirculated water, etc).

Trade Irritants

Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Limits (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern.

Water Quality

Lauryl sulfate salts is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act, based on information provided at

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http://iaspub.epa.gov/tmdl waters10/attains nation cy.cause detail 303d?p cause group_id=885. In addition, no Total Maximum Daily Loads (TMDL) have been developed for DTEA-HCl or DTEA, based on information provided at http://iaspub.epa.gov/tmdl waters10/attains nation.tmdl pollutant detail?p pollutant group_id=885&p_pollutant group_name=PESTICIDES. More information on impaired water bodies and TMDLs can be found at http://www.epa.gov/owow/tmdl/. The Agency invites submission of water quality data for this pesticide. To the extent possible, data should conform to the quality standards in Appendix A of the OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process (see: http://www.epa.gov/oppfead1/cb/ppdc/2006/november06/session1-sop.pdf), in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

Environmental Justice

The EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to sodium lauryl sulfate, compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.

Structure Activity Relationships

EPA must rely upon information of appropriate quality and reliability for each decision made by the Agency. In the Office of Pesticide Programs (OPP), the evaluation process for a pesticide chemical traditionally begins with the applicant's submission of a set of studies conducted with the specific pesticide chemical of interest. The use of the results of such testing (measured data) is a logical, scientifically rigorous process that identifies the physical, chemical, and environmental fate properties of the pesticide, as well as the dose and endpoints at which an adverse effect can occur in various animal species.

Today, there is significant interest in alternative techniques, i.e., techniques other than data generation that could significantly inform the Agency's decision-making process. Recently, OPP has made increasing use of structure activity relationship (SAR) as part of its regulatory decision-making process. In the SAR process, a chemical's molecular structure is compared to that of other chemicals for which data are available. These structural similarities are then used to make predictive judgments about a chemical's physical, chemical, and biological properties. Thus, the chemical's physical, chemical, and biological properties are a function of (or directly related to) the chemical's molecular structure. Quantitative SAR is referred to as QSAR. To develop a QSAR, a

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selected set of measured data on a single physical, chemical, or biological property is used to derive a model (an equation) to predict the value of that property.

Since SAR assessments and QSAR modeling are another set of tools that are available to Agency scientists, OPP has begun a process shift that envisions shifting from the current study-by-study approach to an approach in which the use of predicted data, generated using validated models, is considered along with information from open literature and studies specifically generated under Part 161 requirements. All relevant information would be considered as part of a weight-of-the-evidence evaluation.

At this time, EPA believes that for certain endpoints, especially physical/chemical and fate properties, that SAR and QSAR might be effectively utilized to fulfill these data requirements for many antimicrobial pesticide chemicals. When considering biological properties, at this time, EPA believes that SAR and QSAR can be most effectively utilized in the evaluation of chemicals that exhibit lower toxicity for human health and/or ecotoxicity parameters. This is appropriate because the risk assessment for lower toxicity chemicals can be stream-lined, i.e., a screening-level assessment procedure rather than multiple tiers of assessments with progressively more data requirements.

If stakeholders believe that submission of data may affect this registration review case for sodium lauryl sulfate, then the Agency invites submission of this information. The submitter would be expected to supply a rationale describing the utility of the information and provide documentation on the scientific validity of the information. The determination that the predicted data fulfills a data requirement would be at the sole discretion of the Agency. Pre-submission consultation with the Agency is encouraged.

Next Steps

After the 90-day comment period closes in March 2010, the Agency will review and respond to any comments received in a timely manner and then issue a Final Work Plan (FWP) for lauryl sulfate salts.

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II. FACT SHEET

Background Information

• Lauryl Sulfate Salts (sodium lauryl sulfate) Registration Review Case Number: 4061

• PC Code: 079011

• CAS Registry Number: 151-21-3

• Registrant: Kimberly-Clark Global Sales, LLC

• First approved for use in a registered product: 1948

• Antimicrobials Division Chemical Review Manager (CRM): Monisha Harris, harris.monisha@epa.gov

• Antimicrobials Division Product Manager (PM): ShaRon Carlisle, carlisle.sharon@epa.gov

Chemical Identity/Structure



Use & Usage Information

For additional usage information and use details please refer to "Appendix A: Use and Usage Information for Lauryl Sulfate Salts (sodium lauryl sulfate) (PC Code 079011)," in this document.

- Household/Domestic Dwellings Indoor Premises Antiviral Tissues
- Sodium lauryl sulfate serves as an intentionally-added inert ingredient in over 370 pesticide products although few of these are antimicrobial products.
- <u>Use Sites</u>: sodium lauryl sulfate has no registered direct food uses. Further, EPA has established exemptions from the requirements of a tolerance for residues of sodium lauryl sulfate in foods [40 CFR 180.940(a), -(b), and -(c)] due to the low toxicity.

Earlier Regulatory Actions

 Lauryl Sulfate Salts (sodium lauryl sulfate) Reregistration Eligibility Decision (RED) Document, 1993 http://www.epa.gov/pesticides/reregistration/status.htm

Human Health Risk Assessment Status

The Agency does not anticipate conducting human health risk assessments or requiring additional data for sodium lauryl sulfate because of the low hazard and low exposure

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associated with the use of sodium lauryl sulfate as a pesticide. Further information on the human health risk assessment is available in the document titled "Lauryl Sulfate Salts. Human Health Effects Scoping Document for the Registration Review Decision," dated December 7, 2009.

Ecological Risk Assessment Status

The Agency does not anticipate conducting further analyses of environmental fate and ecological risk or requiring additional data because of the low hazard and low exposure associated with the use of sodium lauryl sulfate as a pesticide. Further information on the environmental fate and ecological risk assessment is available in the document titled, "Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Lauryl Sulfate Salts Registration Review Decision Document," dated October 15, 2009.

Based on the low hazard and exposure the Agency anticipates concluding that the registered uses of sodium lauryl sulfate will have "no effect" (NE) on endangered or threatened terrestrial or aquatic species, or their designated critical habitats, as listed by the U.S. Fish and Wildlife Service (USFWS) and the National Oceanic and Atmospheric Administration's (NOAA) National Marine Fisheries Service (NMFS). EPA anticipates conducting no further analysis of potential risks to endangered or threatened species unless public comments provide additional information that would alter the Agency's current position that sodium lauryl sulfate will have "no effect" on such species or their designated critical habitat.

Data Call-In Status

- In September of 1993, EPA issued a GDCI (generic data call-in) for product chemistry data (data requirements satisfied).
- In January of 1994, EPA issued a GDCI for product chemistry data (data requirements satisfied), ecological effects data (data requirements satisfied) and environmental fate data (data requirements satisfied).

Labels

There is one registered product in the lauryl sulfate salts registration review case. The product registration number is listed below. Product registration labels may be obtained from the Pesticide Product Label System (PPLS) website at: http://oaspub.epa.gov/pestlabl/ppls.home

Table 4: Registered Active Products of Lauryl Sulfate Salts

| Registration Number | Product Name | Company Name |
|----------------------------|----------------------------------|--------------------------------------|
| 9402-10 | Kleenex® Brand Anti-Viral Tissue | Kimberly Clarke Global Sales, LLC |

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III. GLOSSARY of TERMS & ABBREVIATIONS

AI Active Ingredient AR Anticipated Residue

ASTM American Society for Testing and Materials AWPA American Wood Preserver's Association

CBI Confidential Business Information
CFR Code of Federal Regulations
cPAD Chronic Population Adjusted Dose
CSF Confidential Statement of Formula

CSFII USDA Continuing Surveys for Food Intake by Individuals

DCI Data Call-In

DEEM Dietary Exposure Evaluation Model

DFR Dislodgeable Foliar Residue
DNT Developmental Neurotoxicity

DWLOC Drinking Water Level of Comparison
EC Emulsifiable Concentrate Formulation
EDWC Estimated Drinking Water Concentration
EEC Estimated Environmental Concentration

EP End use Product

EPA Environmental Protection Agency

EUP End-Use Product

FDA Food and Drug Administration

FIFRA Federal Insecticide, Fungicide, and Rodenticide Act

FFDCA Federal Food, Drug, and Cosmetic Act

FQPA Food Quality Protection Act FOB Functional Observation Battery

GENEEC Tier I Surface Water Computer Model

IR Index Reservoir

LC₅₀ Median Lethal Concentration. A statistically derived concentration of a substance that can be

expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg

or ppm.

LD₅₀ Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50%

of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal,

e.g., mg/kg.

LOC Level of Concern

LOAEL Lowest Observed Adverse Effect Level

μg/g Micrograms Per Gram μg/L Micrograms Per Liter

mg/kg/day Milligram Per Kilogram Per Day

mg/L Milligrams Per Liter MOE Margin of Exposure

MRID Master Record Identification (number). EPA's system of recording and tracking submitted studies.

MUP Manufacturing-Use Product

NA Not Applicable

NAWQA USGS National Ambient Water Quality Assessment NPDES National Pollutant Discharge Elimination System

NR Not Required

NOAEL No Observed Adverse Effect Level OPP EPA Office of Pesticide Programs

OPPTS EPA Office of Prevention, Pesticides and Toxic Substances

PAD Population Adjusted Dose

PAIRA Pure Active Ingredient Radiolabelled

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PCA Percent Crop Area

PDP USDA Pesticide Data Program PHED Pesticide Handler's Exposure Data

PHI Preharvest Interval
phr Pounds Per Hundred
ppb Parts Per Billion

PPE Personal Protective Equipment

ppm Parts Per Million

PRZM/EXAMS Tier II Surface Water Computer Model

Q₁* The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model

RAC Raw Agriculture Commodity
RED Reregistration Eligibility Decision

REI Restricted Entry Interval

RfD Reference Dose RQ Risk Quotient RTU Ready to Use

SCI-GROW Tier I Ground Water Computer Model

SAP Science Advisory Panel

SF Safety Factor

SLN Special Local Need (Registrations Under Section 24©) of FIFRA)

TGAI Technical Grade Active Ingredient

TEP Typical End-Use Product

USDA United States Department of Agriculture

UF Uncertainty Factor

WPS Worker Protection Standard

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Appendix A: Use and Usage Information for Lauryl Sulfate Salts (Sodium Lauryl Sulfate) (PC Code 079011)

| Use Site | Formulation/ EPA Reg. No. | Method of Application | Application Rate/ No. of applications | Use Limitations | |
|--|--|--------------------------|---------------------------------------|-----------------|--|
| Residential and Public Access Pr | Residential and Public Access Premises | | | | |
| Household/Domestic Dwellings Indoor Premises - Tissues | Impregnated materials 9402-10 | Wipe | Use only as a facial tissue. | | |